

Attorney Docket No. B0048-US02

REMARKS

In response to the Final Action mailed May 6, 2003, Applicants have hereby amended claims 1 and 4-6. No other claims are hereby amended, added or cancelled. Claims 1 and 3-11 thus remain in this case and in issue. The objections/rejections of the Final Action shall now be addressed *seriatim*.

* * *

Claims 1-3 and 6-8 stand rejected pursuant to 35 USC §103(a) as being unpatentable over WO95/01842. Applicants respectively traverse this rejection.

Applicants' claim 1, as amended, requires that the step of "transferring said fraction through said outlet tube occurs upon activation of said centrifuge valve into open position during centrifugation" (emphasis added). WO95/01842 does not disclose activation of a valve into an open position during centrifugation. This feature is not enabled by (and thus not anticipated by) and, moreover, is not suggested by the plain wording of WO95/01842. Rather, the clamping/valving of WO95/01842 may be interpreted plainly as being "normally open," thus not requiring any "activation" from a closed state to an "open position" for the transfer of a fluid therethrough. Thus, although an open state is necessary for the clamp/valve of WO95/01842 for fluid transfer; "activating" such a valve to such a state is not a "necessary step" as asserted in the Final Action (see Final Action, page 2, lines 13-14). Note, programmed or photocell control of the clamp valve(s) in WO95/01842 does not require or necessitate an activating to open interpretation because these "controls" may arguendo be used to merely close a normally open valve (indeed this is what is desired when an approaching interface/boundary surface is sensed in tube 3, the photocell would then trigger the closing of the clamp valve and thereby halt the flow of fluid through tube 3 from the outer bag 1 to the inner bag 2). Activating open, thus not being necessary, is also not suggested by WO95/01842, and WO95/01842 does not render obvious a claim which requires such an action. (Note, it may be that "activating" to an open state is within the scope of WO95/01842, and it is not Applicants' position to foreclose such an interpretation;

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however, it is Applicants' position that nothing in WO95/01842 requires the affirmative action of opening a valve/clamp before fluid transfer, and thus the suggestiveness necessary for the obviousness of affirmative activation is also not established.)

Moreover, this "activating" concept (Final Action, page 2, lines 13-15) has apparently been agreed as not being in or suggested from WO95/01842 itself, and rather has only been asserted as being "obvious to a person of ordinary skill in the art" (see Final Action, page 2, lines 15-16). However, Applicants respectfully assert that this does not set forth a proper basis for such an extension in or from the art. No proper reference was cited for the proposition that such an "activation" of the valve would have actually been obvious for a person of ordinary skill in the art. Therefore, reliance on such an unsupported supposition is improper and is respectfully requested to be withdrawn. Please see *MPEP* 2143.01 (February 2003) at p. 2100-126:

"FACT THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS.

"A statement that modifications of the prior art to meet the claimed invention would have been " 'well with the ordinary skill of the art at the time the claimed invention was made' " because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App & Inter. 1993). [emphasis in the original]

Applicants also respectfully point to *MPEP* 2144.03, pp. 2100-131 – 2100-133; where it is noted how "common knowledge" or "well known" concepts may be relied upon from the prior art. Substantial evidence is required, and although Official Notice may be taken, the reasoning of such must be clear and unmistakable. Such is not the case here, where the prior art, WO95/01842, is clearly susceptible of a completely contrary interpretation (i.e., that the valve or clamp thereof is normally open during use, the programming and/or optical cells being arguendo used to close same). Thus, per 37 CFR

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I.104(d)(2), the Patent Office must provide concrete evidence of the contested allegation (may be by affidavit or declaration) (see also, *MPEP* 2144.03 at p. 2100-133).

Note further for claims 3 and 6-8; because all of these are dependent claims which have incorporated therein all of the limitations of independent claim 1, and because this independent claim 1 is allowable as described above, then as such these dependent claims are allowable as described for the independent claim. As stated in *MPEP* 2143.03, where "an independent claim is nonobvious . . . then any claim depending therefrom is non-obvious."

The obviousness rejections of Claims 1-3 and 6-8 under 35 U.S.C. §103(a) have hereby been obviated and/or traversed and can be withdrawn and these claims may then be noted allowed. Reconsideration and action to this end is respectfully requested.

Next, Claims 9-11 also stand rejected pursuant to 35 USC §103(a) as being unpatentable over WO95/01842 as applied to claim 1 above, and further in view of U.S. Patent No. 5,116,308 (hereafter Hagiwara).

First, reconsideration of this rejection under 35 USC §103(a) is respectfully requested for the reasons set forth with respect to claim 1 above from which these claims depend. Again, because all of these are dependent claims which have incorporated therein all of the limitations of independent claim 1, and because this independent claim 1 is allowable as described above, then as such these dependent claims are allowable as described for the independent claim. As stated in *MPEP* 2143.03, where "an independent claim is nonobvious . . . then any claim depending therefrom is non-obvious."

As to Hagiwara, there has been established no proper basis for combination of Hagiwara with WO95/01842, thus, the rejection based thereon is improper and should be withdrawn. There is no legally or logically acceptable teaching or suggestion that the clamps and/or valves of Hagiwara could or should be combined with or into the cell separation described in

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WO95/01842, or vice versa, particularly not so as to provide a cell separation process as claimed here. As stated in the *MPEP* 706.02(j), second full paragraph, page 700-45 (8th Edition, Rev. 1, February 2003); a *prima facie* case of obviousness requires the establishment of three criteria: 1) a suggestion or motivation to modify or combine reference teachings, 2) a teaching of a reasonable expectation of success, and 3) a teaching of all of the claim limitations. There is no suggestion or motivation in the Hagiwara reference to combine it with WO95/01842, nor in WO95/01842 to combine its teachings with Hagiwara. Note, the clamp and/or valve in WO95/01842 as well as in the presently claimed case is in/on a spinning centrifuge rotor. Nothing in or from Hagiwara suggests that any of the clamps or valves of Hagiwara would be compatible with use in/on a spinning rotor. Communication of power and/or control signals to a spinning valve is a problem, the solution to which not being suggested by a completely static valve/clamp set in or from Hagiwara. Activation during centrifugation is required by Applicants' claims, and nothing in or from Hagiwara or WO95/01842 suggests combination to physically achieve such a feat, nor further any expectation of any success therefor as is also required by *MPEP* 706.02(j) (see above). Therefore the *prima facie* case of obviousness has failed here.

The obviousness rejections of Claims 9-11 under 35 U.S.C. §103(a) have hereby been obviated and/or traversed and can be withdrawn and these claims may then be noted allowed. Reconsideration and action to this end is respectfully requested.

* * *

The notation of allowable subject matter in claims 4 and 5 is noted. The objection to claims 4 and 5 is hereby obviated by the above-described allowability of independent claim 1, the claim from which claims 34 and 5 depend. Withdrawal of this objection is thus respectfully requested.

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The objections/rejections presented in the Final Action of May 6, 2003 have hereby been fully obviated/traversed, and can thus be withdrawn. Action to this end is respectfully requested so that claims 1 and 3-11 may then be allowed and passed to issue.

It is believed that no fee is due for the filing this Amendment. However, please charge deposit account 03-2316 if any other fee is determined to be necessary, considering this statement as authorization to charge any such fee to said account.

If there are any questions, or if prosecution can be expedited in any manner by a telephonic conference, the Examiner is urged to call the undersigned at the below-printed telephone number.

July 7, 2003
Date

Respectfully submitted,



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